



141-424

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT OPERATION

In re Application of:

**Kositprapa et al.**

Serial No.: 10/664,803

Group Art Unit: 1614

Filed: September 19, 2003

Examiner: N/A

For: **NOVEL PHARMACEUTICAL FORMULATION CONTAINING  
A BIGUANIDE AND A THIAZOLIDINEDIONE DERIVATIVE**

New York, NY 10036  
February 28, 2006

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

The following statement of relevance is submitted with the accompanying

Form PTO/SB/08A.

Document  
Designation

Relevance

BO  
U.S. 6,099,862

Relates to oral dosage form for the controlled release of a biguanide and sulfonylurea.

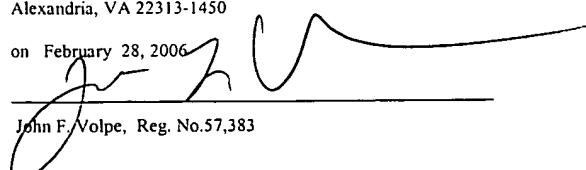
BP  
U.S. 2003/0077297

Relates to pharmaceutical formulations and systems for improved absorption and multistage release of active ingredients.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

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on February 28, 2006

  
John F. Volpe, Reg. No. 57,383

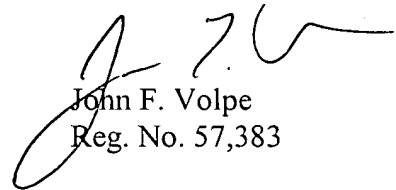
<u>Document Designation</u>	<u>Relevance</u>
BQ U.S. 2003/0224046	Relates to unit dose combination composition for the simultaneous delivery of a short-acting and long-acting oral hypoglycemic agent.
CU WO 99/47125	Relates to method of treating a bacterial infection comprising amoxicillin and potassium clavulanate.
CV EP 1 588 708 A1	Relates to process for producing coated preparation and specifically to applying an immediate release layer of pioglitazone to a metformin core. See Examples 7 and 10 and Experimental Examples 1 and 2.
DN Abdallah et al. Preparation and Evaluation of Metformin Hydrochloride Controlled-Release Tablets STP Pharma 4(1) pp. 15-20, 1988.	Relates to metformin dosage formulation.

In accordance with current Patent and Trademark Office practice, no copy of the above listed United States Patents or applications are filed herewith as well as copies of abstracts in English. Full text copies of all non-United States Patent prior art are enclosed herewith.

It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein. It is believed that no fee is required for submission of this Information Disclosure Statement under 37 C.F.R. §1.97(b). However, if a

fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,



John F. Volpe  
Reg. No. 57,383

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Art Unit	1614
		Examiner Name	Not yet assigned
Sheet 2	of 2	Attorney Docket Number	141-424

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	DN	ABDALLA ET AL, Preparation and evaluation of Metformin Hydrochloride Controlled-Release Tablets, STP Pharma 4(1) pp. 15-20, 1988.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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